DOCUMENT-IDENTIFIER: US 4554686 A
TITLE: Polymethylmethacrylate bone cements and methods for preparing such bone
cements

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4554686

TTL:
Polymethylmethacrylate bone cements and methods for preparing such bone cements

ABPL:
The present invention is directed to polymethylmethacrylate bone cement that is
premixed and frozen so as to arrest the polymerization reaction at a suitable
point. The frozen bone cement is treated by electromagnetic radiation to
insure sterility. In use, the bone cement is warmed until it reaches a
temperature and consistency suitable for use. The bone cement may be
prepackaged in a syringe, or may be molded for use in connection with a
particular prosthesis, or may be packaged unitarily with a prosthesis.

BSPR:
The present invention is related to improved bone cements and methods for
preparing such bone cements. More particularly, the present invention is
directed to improved polymethylmethacrylate bone cements for securing metal and
plastic prostheses to bone and to the methods of preparing such bone cements.

BSPR:
Surgical procedures to reconstruct or repair bones have become extremely
common. For instance, a variety of prostheses are commercially available for
use in repairing damaged hip joints or knee joints due to such diseases as
osteoarthritis, rheumatoid arthritis, traumatic arthritis, avascular necrosis,
and sickle cell anemia osteoporosis. In these procedures, the prosthesis is
typically cemented in place by use of a polymethylmethacrylate bone cement.

BSPR:
Polymethylmethacrylate is a self-curing acrylic resin; it polymerizes at room
temperature without any external application of heat. Polymethylmethacrylate
bone cement comes to the surgeon in a kit form consisting of two components
that must be mixed together to initiate polymerization.

BSPR:
The first component is a liquid mixture comprising monomeric methyl
methacrylate together with a small amount of N,
N-dimethyl-p-toluidine to
induce setting of the mixed cement, and hydroquinone to inhibit self-polymerization of the monomer liquid. The second kit component is a
polymer powder including polymethylmethacrylate. Frequently, the radiopaque
compound barium sulfate is also included in the powder component to serve as an
opacifier, and some commercial formulations include benzoyl peroxide as a
catalyst to the polymerization reaction. Some commercial compositions of
polymer powder also include substantial amounts of methylmethacrylate-styrene
copolymer; this copolymer is believed to improve the mixing qualities of the
cement.

BSPR:
Polymethylmethacrylate is a "luting" agent, rather than an adhesive; this
cement does not produce any chemical bond with bone tissue to hold the
prosthesis in place, but rather fills irregularities in the bone and hardens to
form a mechanical interlock.

BSPR:
The most often-used technique for reconstructing damaged bone

tissue involves
initially preparing the bone tissue by cutting and drilling the bone tissue so
that it conforms to the shape of the securement portion of a prosthesis. Then,
a number of shallow holes are generally drilled or cut into the surfaces of the
bone tissue adjacent to the prosthesis in order to form projecting cavities
into which cement will flow so as to form a strong mechanical interlock between
the bone cement and the bone tissue.

BSPR:
The prepared bone surfaces are then thoroughly cleansed of all blood, fatty
marrow tissue, bone fragments, and the like, so that the cement will conform to
all of the surface irregularities of the prepared bone tissue. Finally, the
two components of the unpolymerized bone cement are mixed.

BSPR:
Once mixing of the bone cement is commenced, it is critical that the surgeon
act quickly; the polymethylmethacrylate bone cement sets up extremely rapidly,
and unless it is used quickly it will not flow into the irregularities and
projecting cavities within the prepared bone tissue. Typically, it takes about
two (2) minutes to prepare the cement for use, and the cement becomes too

viscous to produce a reliable bond if it is not used within about five (5) or
six (6) minutes.

BSPR:
It will be appreciated that the need for haste is extremely disadvantageous.
As the bone cement continues to harden, a delay of only seconds might mean the
difference between success and failure. A host of occurrences, such as the
need to further cleanse the prepared bone tissue, or a fluctuation in the
patient's vital signs, or failure of the surgeon or his assistants to work
quickly enough, can easily cause precious time to be lost. Unfortunately, the
success or failure of the procedure is learned only later when the bond fails
because of poor mechanical attachment to the bone tissue.

BSPR:
In addition to the problems associated with conventional bone cements mentioned
above, working with the various components of bone cement can be hazardous to
the health of the individuals involved in its preparation and use. For
instance, the liquid monomer is a highly volatile substance and is known to be
irritating to the respiratory tract, eyes, and the liver. Since as much as 15%
of the liquid monomer evaporates during the mixing step, the

concentration of
monomer vapor in the vicinity of the person doing the mixing can be high enough
to cause injury. This is particularly true over prolonged periods of time due
to the cumulative effects where the same person mixes batch after batch of the
bone cement in operation after operation.

BSPR:
In addition to hazards to operating room personnel, the use of bone cement also
frequently causes injury to the patient's bone tissue. For instance, the
polymerization reaction is highly exothermic, and the temperature of the cement
can climb to as much as 110.degree. C. during the polymerization process.
Temperatures in the range of 70.degree. C. to 80.degree. C. are common.

BSPR:
One frequent source of failure of the prosthetic reconstruction is due to
tissue necrosis at the bone-cement interface; a thin fibrous layer often forms
at the interface between the cement and bone, and this tissue sometimes results
in so much loosening of the prothesis that a second surgical operation is
required.

BSPR:

Because of the foregoing problems, some surgeons have attempted to entirely
avoid the use of bone cement by devising other mechanical attachment methods.
Moreover, a great deal of effort and expense has been directed at attempts to
provide such improved attachment methods. Other research has been directed to
the development of improved bone cement formulations. However, these attempts
have proved largely unavailing, and most surgeons continue to utilize
polymethylmethacrylate in the maner described above, despite the serious
problems connected with its use.

BSPR:
From the foregoing, it will be appreciated that it would be a significant
advancement in the art of securing prostheses to bone by use of
polymethylmethacrylate bone cement to provide methods and apparatus capable of
extending the time available to a surgeon preparatory to placing the cement and
prosthesis. It would also be a significant advancement if the hazards to
operating room personnel due to the toxicity of constituents of uncured
polymethylmethacrylate could be alleviated. It would also be very significant
if improved sterile techniques could be provided for preparing the cement for
placement, and if tissue necrosis at the bone-cement interface due

to high
temperatures could be reduced. It would further be a significant advancement
if cement could be mixed in a manner that led to more predictable and
reproducible results. Such advancements in the art are described and claimed
herein.

BSPR:
The present invention is directed to methods and apparatus relating to the use
of polymethylmethacrylate bone cement in the reconstruction of damaged bone
tissue. In accordance with the present invention, damaged bone tissue is
prepared to accept a suitable prosthetic device, which is secured in place by
use of bone cement that had been premixed, but frozen to arrest polymerization.

BSPR:
Use of premixed frozen bone cement avoids the need to mix the bone cement in
the operating room, thereby freeing surgical assistants for other tasks, and
eliminating the health hazard associated with such mixing. The lower
temperatures involved also extend the time available to the surgeon within
which to place the bone cement. By permitting the premixed bone cement to be
prepared under controlled manufacturing conditions, the frozen

bone cement will
have a predictable consistency and composition that will maximize the
probability of a successful reconstruction operation. Moreover, preparation of
the bone cement in a carefully controlled manner substantially decreases the
likelihood of harmful effects to operating room personnel from long-term
exposure to bone cement.

BSPR:
Another feature of the present invention is the ability to sterilize the
premixed bone cement while in frozen form by treatment with suitable
electromagnetic radiation, such as gamma radiation from a cobalt-60 source.
Such sterilization minimizes the likelihood of introducing infection into the
restoration site.

BSPR:
It is, therefore, a primary object of the present invention to provide methods
and apparatus for extending the time available to a surgeon during bone
reconstruction surgical procedures within which to place bone cement and an
associated prosthesis.

BSPR:
It is another object of the present invention to provide methods and

apparatus
that minimize health hazards to operating room personnel occasioned by use of
polymethylmethacrylate bone cement.

BSPR:
Yet another object of the present invention is to provide methods and apparatus
that minimize the extent of damage to the patient's bone tissue resulting from
the heat generated by bone cement as it cures.

BSPR:
Still a further object of the present invention is to provide methods and
apparatus that insure the sterility of bone cement used in reconstruction
surgical procedures.

BSPR:
Yet a further object of the present invention is to provide methods and
apparatus for preparing bone cement having a reproducible consistency,
composition, and properties.

DEPR:
The present invention provides methods and apparatus that avoid many of the
problems inherent in conventional use of polymethylmethacrylate bone cement to
secure surgical prostheses to living bone.

DEPR:
As mentioned above, once bone cement has been mixed, the surgeon typically has only about three to four minutes within which to properly place the bone cement and the prosthesis before the cement becomes so viscous that it is incapable of forming a reliable mechanical bond with the bone tissue. One feature of the present invention is the extension of the amount of time the surgeon has within which to place the cement and prosthesis, and the corresponding termination of the need for haste in this phase of the reconstruction procedure.

DEPR:
These benefits are obtained by providing the bone cement to the surgeon in a different form than that of conventional practice. Thus, in accordance with the present invention, rather than providing the surgeon with cement components that must be prepared in the operating room for use, the surgeon is provided with premixed cement that has been quick-frozen to temporarily halt the polymerization reaction.

DEPR:
It is possible to halt the polymerization reaction at virtually any point along the polymerization process. Thus, polymerization can be permitted to progress

to a point that is optimum for a particular purpose, and then the bone cement
may be rapidly frozen to arrest the polymerization reaction at precisely that
point. Because the mixing of the bone cement that is to be frozen for later
use can be conducted under controlled conditions, it is possible to insure that
virtually every portion of frozen bone cement is substantially identical to
every other portion in terms of composition and extent of polymerization. This
removes yet one more variable encountered by the surgeon, thereby greatly
improving the likelihood of a successful reconstruction.

DEPR:
Another significant advantage of premixing the bone cement in controlled
conditions is the improved ability to provide sterile bone cement under those
conditions. Thus, the manufacturing process can be specifically designed for
production of bone cement; this is in marked contrast to the conventional
situation wherein the mixing step is merely one activity among many in a busy
operating room.

DEPR:
As a result, the mixing process can be arranged in a manner most conducive to
preparation of bone cement. The mechanization of the mixing

process would by
itself assist greatly in improving the quality and sterility of bone cement.
Further, a technician responsible for mixing the bone cement under controlled
conditions will become especially proficient in mixing bone cement so as to
conform to desired standards, including standards of sterility.

DEPR:
As indicated above, the polymerization reaction can be stopped at virtually any
selected point by subjecting the bone cement to rapid freezing. It has been
discovered that such freezing does not adversely affect the polymethylmethacrylate bone cement, and such cement will resume polymerization
upon warming.

DEPR:
Because of its low expense and ready availability, it is preferred that liquid
nitrogen be utilized to effect rapid freezing of the partially polymerized bone
cement. Liquid nitrogen is extremely advantageous for this purpose because of
its low temperature, and also because of its being in a liquid form that
readily conforms to the outline of the bone cement and quickly conducts heat
from the bone cement. In practice, the bone cement may simply be dropped into
a container of liquid nitrogen and left until the liquid nitrogen

ceases to
"boil"; at this point the cement will be completely frozen.

DEPR:
It will be appreciated that other materials can be used to effect freezing of
the bone cement in lieu of liquid nitrogen. However, it is preferred that such
a material be capable of reducing the temperature of the bone cement to the
point where polymerization is arrested within about ten to fifteen seconds.

DEPR:
It has been discovered that bone cement may be stored for extended periods at
temperatures warmer than liquid nitrogen temperatures. For instance, frozen
polymethylmethacrylate bone cement can be stored indefinitely at dry ice
temperatures (about -80.degree. C.). This greatly facilitates shipment of
frozen bone cement, and also raises the temperature of the bone cement closer
to its melting temperature (about -5.degree. C.), thereby reducing the extent
of warming necessary to resume polymerization. It has also been found that
partially polymerized polymethylmethacrylate bone cement can be stored at
conventional freezer temperatures (-70.degree. C.) for extended periods. In
contrast, it has been found that at a higher temperature of about

-30.degree.
C., a significant amount of polymerization occurs over extended periods making
long-term storage of frozen bone cement at this temperature undesirable.

DEPR:
As mentioned above, the act of mixing the bone cement under controlled
manufacturing conditions greatly facilitates good sterile technique. However,
it has been discovered that frozen bone cement may be subjected to gamma
radiation, such as from a Cobalt-60 source, or to an electron beam, to
virtually guarantee sterile conditions. Thus, it has been found that bone
cement held at a temperature between about -50.degree. C. and -135.degree. C.
can be sterilized by irradiation with gamma radiation without undergoing any
substantial degree of polymerization. At temperatures below about -135.degree.
C., gamma radiation is ineffective to effect sterilization because bacterial
spores become biologically inert below that temperature. The effectiveness of
gamma radiation as a sterilization agent increases as the temperature of the
frozen bone cement is raised. However, as the temperature is raised above
about -50.degree. C., significant amounts of polymerization are induced during

sterilization. Accordingly, it is preferred that sterilization by gamma ray
radiation be effected at temperatures below about -50.degree. C. It is
feasible to premix bone cement with clean rather than sterile technique, and
using components that have not been previously sterilized, and yet insure
sterility of the bone cement supplied to the surgeon.

DEPR:
In connection with existing prior art bone cements, the powder component of
unmixed bone cement is generally sterilized by gamma irradiation, but because
the monomer will degrade if subjected to gamma radiation, the monomer liquid is
generally sterilized by filtration through a bacterial filter. The subjection
of frozen premixed bone cement to gamma radiation could avoid the need to
subject the monomer liquid to sterilization on a bacterial filter.

DEPR:
Because the premixed bone cement can be frozen at virtually any stage in the
polymerization process, it is possible to provide bone cement having suitable
characteristics for any particular application. For instance, in those types
of reconstruction procedures where it is preferred to inject semi-liquid bone
cement into a restoration site by means of a syringe, it is possible

to freeze
the premixed bone cement before any substantial amount of polymerization has
occurred. Advantageously, the bone cement may be loaded into a syringe or
syringe cartridge before freezing, thereby avoiding the need for additional
handling by the surgeon or his assistants.

DEPR:
Alternatively, the bone cement can be permitted to undergo a further degree of
polymerization before being frozen. For instance, the premixed bone cement can
be taken into the "dough" state before being frozen. It will be appreciated
that other alternatives are also available.

DEPR:
In use, the frozen bone cement is withdrawn from a freezer in the operating
room (typically maintained at about -70.degree. C.) after the restoration site
has been prepared and cleansed. It has been found that the premixed bone
cement is a good thermal conductor, and rapidly warms to the point where
polymerization recommences. Once polymerization recommences, the heat
generated by that exothermic process assists in warming the bone cement to the
point where it becomes malleable. Typically, frozen bone cement can be warmed

in the hands of the surgeon (wearing surgical gloves) from freezer temperatures
to the point where it is ready for use in only about one or two minutes.

DEPR:
As explained above, one disadvantage of current techniques involving bone
cement is the frequent occurrence of bone tissue necrosis due to the heat
generated by the polymerizing bone cement. The present invention substantially
avoids this adverse event in two ways. First, the heat generated prior to the
point where the premixed bone cement is frozen is completely removed from the
system. Thus, only that amount of heat that is generated after resumption of
polymerization is of concern, and this factor alone can result in a substantial
temperature reduction at the cement-bone tissue interface.

DEPR:
Second, the bone cement will generally be placed into the restoration site
while it is still rather cool; heat initially generated by the polymerization
reaction is used in warming the bone cement up to room temperature. Since only
a particular amount of heat is generated by a particular mixture of bone
cement, yet further decreases will be observed in the maximum temperature

reached within the reconstruction site at the bone cement-bone tissue
interface.

DEPR:
As indicated above, an important feature of the present invention is avoidance
of the requirement for undue haste in the operating room. Even as the
polymerization reaction recommences upon warming, it is initially much slower
than the normal polymerization rate at room temperature. Then, because the
temperature of the mixture remains lower throughout the process than is
observed at corresponding conditions of polymerization in connection with
conventional use of bone cement, there is a significantly extended period of
time between thawing of the cement to the point where it may be used, until the
bone cement becomes too viscous for reliable use. By increasing the period
within which the cement is capable of forming a reliable bond, the likelihood
of success of the reconstruction is substantially increased.

DEPR:
The use of frozen bone cement is also advantageous because it eliminates the
primary health hazard to operating room personnel--breathing of the monomer
vapor during the mixing step in the operating room.

DEPR:
Further, by providing the bone cement to the surgeon in a form already
polymerized to the desired extent, there is little or no need for handling by
the physician other than to mold it to a desired shape and to effect placement.
Thus, the dangers of contact dermatitis which are associated with prior art
bone cements are avoided. Another feature of the present invention is the
ability to provide bone cement in preformed condition that will conform to a
typical bone preparation and corresponding prosthesis. It is quite practical
to mold premixed bone cement in the laboratory prior to freezing. Thus, the
surgeon using premolded frozen bone cement need only place the warmed cement
into position in the reconstruction site without any significant handling of
the material. This procedure not only increases the likelihood of successful
attachment of the prothesis, but it also minimizes handling of the bone cement.

DEPR:
It will be appreciated that for many surgical procedures it will be advantageous to sell the bone cement and the associated prosthesis as a unit,
with the frozen bone cement already secured to the prosthesis. For instance,

the molded bone cement can be frozen and then mounted on the prosthesis, or the
premixed cement can be molded around the prosthesis while curing, and then both
the cement and prosthesis subjected to temperatures sufficient to freeze the
bone cement and arrest the polymerization reaction.

DEPR:
From the foregoing, it will be appreciated that the present invention for the
first time presents the surgeon with bone cement that will have characteristics
that are reproducible from batch to batch. No longer will variations in mixing
technique, or differences in mixing time cause variations in the rate and the
extent of polymerization of the cement placed into a reconstruction site. No
longer will the surgeon be subjected to the requirement for undue haste from
the moment he orders the cement mixed, wherein he must insure that the cement
is mixed, molded, and installed together with the prosthesis in the reconstruction site, all within no more than five to six minutes.

DEPR:
Rather, in accordance with the present invention, the surgeon can order removal
of frozen premixed bone cement from the freezer, knowing that it will have the
proper consistency. Further, short delays will not result in the bone cement

becoming too viscous for use, since the lower temperatures involved slow down
the rate of polymerization, thereby substantially increasing the time available
to the surgeon within which to place the bone cement in the desired location.

DEPR:
The present invention is also safer for operating room personnel than
conventional techniques since no substantial amounts of monomeric liquid are
permitted to evaporate into the air, and since the amount of handling by the
surgeon and assistants is minimized. Use of frozen bone cement is safer to the
patient because there is significantly less probability of introducing an
infection with the bone cement, and because the likelihood and extent of bone
tissue necrosis due to high temperatures of polymerization is significantly
lessened.

CLPR:
1. A method for preparing polymethylmethacrylate bone cement for use in
attaching a surgical prosthesis to prepared bone tissue, the method comprising
the steps of:

CLPR:
2. A method for preparing polymethylmethacrylate bone cement

as defined in
claim 1, wherein the freezing step is accomplished by placing the partially
polymerized bone cement into freezing means capable of effecting rapid freezing
of the bone cement.

CLPR:
3. A method for preparing polymethylmethacrylate bone cement as defined in
claim 2, wherein said rapid freezing of the bone cement is effected in less
than about 15 seconds.

CLPR:
4. A method for preparing polymethylmethacrylate bone cement as defined in
claim 1, wherein the freezing step is accomplished by submerging the partially
polymerized bone cement in liquid nitrogen.

CLPR:
5. A method for preparing polymethylmethacrylate bone cement for use in
attaching a surgical prosthesis to prepared bone tissue, the method comprising
the steps of:

CLPR:
6. A method for preparing polymethylmethacrylate bone cement for use in
attaching a surgical prosthesis to prepared bone tissue, the method comprising

the steps of:

CLPR:
7. A method for preparing polymethylmethacrylate bone cement for use in
attaching a surgical prosthesis to prepared bone tissue, the method comprising
the steps of:

CLPR:
8. A method for preparing polymethylmethacrylate bone cement as defined in
claim 1, wherein the electromagnetic radiation is gamma radiation.

CLPR:
9. A method for preparing polymethylmethacrylate bone cement as defined in
claim 8, wherein the gamma radiation is from a cobalt-60 source.

CLPR:
10. A method for preparing polymethylmethacrylate bone cement as defined in
claim 8, wherein the frozen bone cement is maintained at a temperature below
about -50.degree. C. during irradiation by gamma radiation.

CLPR:
11. A method for preparing polymethylmethacrylate bone cement as defined in
claim 1, wherein the electromagnetic radiation is an electron beam.

CLPR:
12. A method for preparing polymethylmethacrylate bone cement

as defined in
claim 2, further comprising the step of placing the frozen bone cement into
temperature maintenance means adapted to maintain the bone cement at a
temperature wherein no substantial amount of polymerization occurs.

CLPR:
13. A sterile frozen bone cement composition including methylmethacrylate and
suitable polymerization initiating agents wherein polymerization has been
initiated but arrested at a desired degree of partial polymerization, said
partially polymerized bone cement composition being placed into syringe means
while in a substantially free-flowing condition and then frozen while in said
syringe means, and wherein the frozen partially polymerized bone cement in the
syringe is maintained at a temperature below about -70.degree. C. until use.

CLPR:
14. A sterile frozen bone cement composition including methylmethacrylate and
suitable polymerization initiating agents wherein polymerization has been
initiated but arrested at a desired degree of partial polymerization, said
partially polymerized bone cement composition being formed into a suitable

shape for use with a particular surgical prosthesis and then frozen, and
wherein the partially polymerized bone cement is maintained at a temperature
below about -70.degree. C. until use.

CLPR:
15. A sterile frozen bone cement composition including methylmethacrylate and
suitable polymerization initiating agents wherein polymerization has been
initiated but arrested at a desired degree of partial polymerization, said
partially polymerized bone cement composition being formed on a surgical
prosthesis and frozen while secured to said prosthesis, and wherein the
partially polymerized bone cement is maintained at a temperature below about
-70.degree. C. until use.

CLPR:
16. A bone prosthesis for use in the repair of damaged bone tissue comprising
a suitable prothesis; and preformed sterile frozen bone cement secured thereto
in a manner such that the prothesis and bone cement may be unitarily placed
into prepared bone tissue to effect repair thereof, said frozen bone cement
being partially polymerized, but having polymerization thereof arrested at a
desired degree of polymerization.

CLPR:
17. A bone prosthesis as defined in claim 16, wherein the prosthesis and
associated bone cement are maintained at a temperature below about -70.degree.
C. prior to use.

CLPR:
18. A method for preparing polymethylmethacrylate bone cement as defined in
claim 5 wherein the freezing step is accomplished by placing the partially
polymerized bone cement into freezing means capable of effecting rapid freezing
of the bone cement.

CLPR:
19. A method for preparing polymethylmethacrylate bone cement as defined in
claim 18, wherein said rapid freezing of the bone cement is effected in less
than about 15 seconds.

CLPR:
20. A method for preparing polymethylmethacrylate bone cement as defined in
claim 5, wherein the freezing step is accomplished by submerging the partially
polymerized bone cement in liquid nitrogen.

CLPR:
21. A method for preparing polymethylmethacrylate bone cement

as defined in
claim 5, wherein the electromagnetic radiation is gamma radiation.

CLPR:
22. A method for preparing polymethylmethacrylate bone cement as defined in
claim 21, wherein the gamma radiation is from a cobalt-60 source.

CLPR:
23. A method for preparing polymethylmethacrylate bone cement as defined in
claim 21, wherein the frozen bone cement is maintained at a temperature below
about -50.degree. C. during irradiation by gamma radiation.

CLPR:
24. A method for preparing polymethylmethacrylate bone cement as defined in
claim 5, wherein the electromagnetic radiation is an electron beam.

CLPR:
25. A method for preparing polymethylmethacrylate bone cement as defined in
claim 18, further comprising the step of placing the frozen bone cement into
temperature maintenance means adapted to maintain the bone cement at a
temperature wherein no substantial amount of polymerization occurs.

CLPR:
26. A method for preparing polymethylmethacrylate bone cement as defined in

claim 6 wherein the freezing step is accomplished by placing the partially
polymerized bone cement into freezing means capable of effecting rapid freezing
of the bone cement.

CLPR:
27. A method for preparing polymethylmethacrylate bone cement as defined in
claim 26, wherein said rapid freezing of the bone cement is effected in less
than about 15 seconds.

CLPR:
28. A method for preparing polymethylmethacrylate bone cement as defined in
claim 6, wherein the freezing step is accomplished by submerging the partially
polymerized bone cement in liquid nitrogen.

CLPR:
29. A method for preparing polymethylmethacrylate bone cement as defined in
claim 6, wherein the electromagnetic radiation is gamma radiation.

CLPR:
30. A method for preparing polymethylmethacrylate bone cement as defined in
claim 29, wherein the gamma radiation is from a cobalt-60 source.

CLPR:
31. A method for preparing polymethylmethacrylate bone cement as defined in

claim 29, wherein the frozen bone cement is maintained at a temperature below
about -50.degree. C. during irradiation by gamma radiation.

CLPR:
32. A method for preparing polymethylmethacrylate bone cement as defined in
claim 6, wherein the electromagnetic radiation is an electron beam.

CLPR:
33. A method for preparing polymethylmethacrylate bone cement as defined in
claim 26, further comprising the step of placing the frozen bone cement into
temperature maintenance means adapted to maintain the bone cement at a
temperature wherein no substantial amount of polymerization occurs.

CLPR:
34. A method for preparing polymethylmethacrylate bone cement as defined in
claim 7 wherein the freezing step is accomplished by placing the partially
polymerized bone cement into freezing means capable of effecting rapid freezing
of the bone cement.

CLPR:
35. A method for preparing polymethylmethacrylate bone cement as defined in
claim 34, wherein said rapid freezing of the bone cement is effected in less

than about 15 seconds.

CLPR:
36. A method for preparing polymethylmethacrylate bone cement as defined in
claim 7, wherein the freezing step is accomplished by submerging the partially
polymerized bone cement in liquid nitrogen.

CLPR:
37. A method for preparing polymethylmethacrylate bone cement as defined in
claim 7, wherein the electromagnetic radiation is gamma radiation.

CLPR:
38. A method for preparing polymethylmethacrylate bone cement as defined in
claim 37, wherein the gamma radiation is from a cobalt-60 source.

CLPR:
39. A method for preparing polymethylmethacrylate bone cement as defined in
claim 37, wherein the frozen bone cement is maintained at a temperature below
about -50.degree. C. during irradiation by gamma radiation.

CLPR:
40. A method for preparing polymethylmethacrylate bone cement as defined in
claim 7, wherein the electromagnetic radiation is an electron beam.

CLPR:
41. A method for preparing polymethylmethacrylate bone cement

as defined in
claim 34, further comprising the step of placing the frozen bone cement into
temperature maintenance means adapted to maintain the bone cement at a
temperature wherein no substantial amount of polymerization occurs.

CLPV:
mixing a bone cement composition including methylmethacrylate with a
composition capable of initiating a polymerization of the methylmethacrylate;

CLPV:
blending the bone cement composition until a desired degree of partial
polymerization has occurred;

CLPV:
placing substantially free flowing partially polymerized bone cement into
syringe means;

CLPV:
freezing the partially polymerized bone cement in order to substantially arrest
polymerization of the methylmethacrylate in the bone cement composition;

CLPV:
irradiating the frozen bone cement with suitable electromagnetic radiation

capable of sterilizing the frozen bone cement without inducing substantial
amounts of polymerization of the methylmethacrylate in the frozen bone cement;
and

CLPV:
storing the sterilized, frozen bone cement at a temperature below about
-70.degree. C. until use of the bone cement.

CLPV:
mixing a bone cement composition including methylmethacrylate with a
composition capable of initiating a polymerization of the methylmethacrylate;

CLPV:
blending the bone cement composition until a desired degree of partial
polymerization has occurred;

CLPV:
forming the partially polymerized bone cement into a suitable shape for use
with a particular surgical prosthesis;

CLPV:
freezing the partially polymerized bone cement in order to substantially arrest
polymerization of the methylmethacrylate in the bone cement composition;

CLPV:
irradiating the frozen bone cement with suitable electromagnetic radiation
capable of sterilizing the frozen bone cement without inducing substantial
amounts of polymerization of the methylmethacrylate in the frozen bone cement;
and

CLPV:
storing the sterilized, frozen bone cement at a temperature below about
-70.degree. C. until use of the bone cement.

CLPV:
mixing a bone cement composition including methylmethacrylate with a
composition capable of initiating a polymerization of the methylmethacrylate;

CLPV:
blending the bone cement composition until a desired degree of partial
polymerization has occurred;

CLPV:
forming the partially polymerized bone cement onto a surgical prosthesis;

CLPV:
freezing the partially polymerized bone cement while formed on the surgical
prosthesis in order to substantially arrest polymerization of the

methylmethacrylate in the bone cement composition;

CLPV:
irradiating the frozen bone cement and prosthesis with suitable electromagnetic
radiation capable of sterilizing the frozen bone cement and the prosthesis
without inducing substantial amounts of polymerization of the methylmethacrylate in the frozen bone cement; and

CLPV:
storing the sterilized, frozen bone cement and prosthesis at a temperature
below about -70.degree. C. until use of the bone cement.

CLPV:
mixing a bone cement composition including methylmethacrylate with a
composition capable of initiating a polymerization of the methylmethacrylate;

CLPV:
blending the bone cement composition until a desired degree of partial
polymerization has occurred;

CLPV:
freezing the partially polymerized bone cement in order to substantially arrest
polymerization of the methylmethacrylate in the bone cement composition;

CLPV:

irradiating the frozen bone cement with suitable electromagnetic radiation
capable of sterilizing the frozen bone cement without inducing substantial
amounts of polymerization of the methylmethacrylate in the frozen bone cement;
and

CLPV:
storing the sterilized, frozen bone cement at a temperature below about
-70.degree. C. until use of the bone cement;

CLPV:
warming the frozen bone cement to a temperature suitable to permit it to be
used to attach a surgical prosthesis to prepared bone tissue.

ORPL:
Zimmer Technical Report on Zimmer Bone Cement, Sep., 1977.